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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,763	12/27/2005	Patrice Mauriac	270,388	8762

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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,763	MAURIAC ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-42* is/are pending in the application.

4a) Of the above claim(s) *30 and 35-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-29 and 31-34* is/are rejected.

7)☒ Claim(s) *26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/12/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Note to Applicant: References to paragraphs in non-patent literature refers to full paragraphs (e.g. 'page 1 column 1 paragraph 1' refers to the first full paragraph on page 1 in column 1 of the reference)

Election/Restrictions

Applicant's election with traverse of Group I where the active ingredient is only in the core in the reply filed on July 14, 2008 is acknowledged. The traversal is on the grounds that the common inventive concept is different than that given by the Examiner and distinct from the prior art cited. This is not found persuasive. Applicant has recited a product-by-process claim that does not confer any additional structural limitation to the final product. Extrusion does not inherently confer a distinct structure that is not obtainable by other methods. Further it is not clear that the process portion of the claim is drawn to the entire core as oppose to just the PLGA used to produce the core. Applicant also argues several limitations that are not in the claims (e.g. continuous structure, spaghetti, release kinetics, degree of coating coverage, etc). IN addition, Applicant argues intended uses of the product (subcutaneous vs. ocular) which do not distinguish one composition over another when both are composed of the same claimed materials. Based upon the components of the product and claimed configuration, the common technical feature described in the restriction requirement is accurate and is taught by the prior art that was cited.

The requirement is still deemed proper and is therefore made FINAL.

Claims 30 and 35-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim.

Specification

The disclosure is objected to because of the following informalities: Applicant discusses US patents to detail the state of the prior art; however, the actual content of one of the citations (U.S. Patent No. 4,768,628) does not align with the subject matter of the instant application (USP 4,768,628 discusses shock absorbers for vehicles).

Appropriate correction is required.

Claim Objections

Claim 27 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Based upon applicant's definition of "essentially consisting of", which is interpreted to be equivalent to "consists essentially of", claim 27 recites a PLGA present at a range of 99.9% to 100% while its parent claim (claim 26) recites a range of 75% to 99.999% (see specification page 11 line 31-page 12 line 1 and page 12 lines 8-9). thus the dependent claim recites a range outside that of its parent.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-24, 27, 32, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "increase" in claim 23 and "extremely" in claim 24 are relative terms which render the claims indefinite. The terms "increase" and "extremely" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Regarding the term "increase", no basis for comparison is provided. Thus there is no way to know which active principles would meet the limitation of being "able to increase bone density" Regarding the term "extremely", the actual boundaries or amount of variation implied is unknown base upon the disclosure. Therefore, the metes and bounds of the claim cannot be ascertained.

Claim 27 is indefinite because it expands the range of PLGA claimed in its parent claim (claim 26). Thus the claim, in essence, redefines the range of PLGA in the coating of the invention.

Claims 32 and 34 use the open ended language, "comprised between," to define a molar ratio range and a thickness range, respectively. According to MPEP 2111.03,

"[t]he transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004)". Based upon this description, the ranges recited as being "comprised between" two values actually recite boundless ranges.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22, 25-27, and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (Pharmaceutical research 1996 13(7):1059-1064 – see IDS).

Wang et al. disclose an implant device comprised of a core and coating where the core contains poly(lactide-co-glycolide) (PLGA) and an active principle dispersed within it, while the coating is the same PLGA used in the core (see page 1059 column 2 paragraph 4-page 1060 column 1 paragraph 2; instant claim 22). The coating is taught applied by dip-coating, thus the polymer forms a film on the core surface (see page

1060 column 1 paragraph 2; instant claim 22). Applicant has claimed a product-by-process, but the process (extrusion) does not imply or add further structural limitations to the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (see MPEP 2113). The claim does not clearly require that the components of the core be extruded together nor delineate any structure conferred to the product that is unique or inherent to extrusion. Thus no structure is added to the product by the product-by-process language. Wang et al. also disclose that the PLGA used has a 75/25 ratio of lactic acid to glycolic acid and a nominal molecular weight of 100,000 (see page 1059 column 2 paragraph 4; instant claims 25 and 31-32). Applicant defines the phrasing "essentially consists of" X to mean that X is present in amounts higher or equal to 99.9% (see instant specification page 11 lines 31-page 12 line 1 and page 12 lines 8-10). The phrase "consists essentially of" X is interpreted to be an equivalent statement. Thus a coating of 100% PLGA consists essentially of PLGA (see page 1060 column 1 paragraph 2 lines 1-2; instant claims 26-27). Since Applicant posed instant claim 27 as a further limitation of instant claim 26, the prior art that teaches instant claim 27 is viewed as also teaching instant claim 26. Therefore claims 22, 25-27, and 31-3 are unpatentable over Wang et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chou et al. (US PGPub No. 2004/0009222).

Chou et al. teach a co-extruded, implantable drug delivery device composed of a core and outer skin (film) configuration (see paragraph 8). The drug is taught present in the core (see paragraph 9). Further, PLGA is taught as the polymer in the core and skin (see paragraphs 10-11, 35 and claims 1, 12 and 13). Based upon these teaches, where PLGA is specifically taught in the core and skin, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have PLGA simultaneously in both regions. Therefore claim 22 is obvious over Chou et al.

Claims 22 , 26, and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chou et al. as applied to claim 22 above, and further in view of Talton (US Patent No. 7,063,748), Belenkaya et al. (US PGPub No. 2003/0069369), and Byon & Yoon (US Patent No. 6,702,850).

Chou et al. teach a co-extruded, implantable drug delivery device composed of a core and outer skin (film) configuration (see paragraph 8). The drug is taught present in the core (see paragraph 9). Further PLGA is taught as the polymer in the core and skin (see paragraphs 10-11, 35 and claims 1, 12 and 13). The outer skin is taught to modify

the release of the drug from the core (see paragraph 35). Chou et al. do not explicitly teach the presence of hydrophilic excipients in the coating film.

Talton teaches polymeric blends applied as coatings to modify the release rate of drug containing solids (see column 7 lines 27-42 and column 21 lines 4-19; instant claim 26). PLGA is particularly preferred as a polymer while polyvinylpyrrolidone (PVP) is also taught as an envisioned polymer in such a coating (see column 7 lines 34-36 and column 21 lines 10-11 and17-19; instant claim 29). Talton does not specifically teach relative proportions of polymers to use in their taught coatings.

Belenkaya teach PLGA and PVP as biodegradable and biocompatible polymers known for use together at an 80/20 ratio in the context of implants (see paragraphs 9 and 41). In addition, Byon & Yoon teach PLGA and PVP in a coating used for drug delivery on an implantable device (see claims 1 and 2). Thus a blend of PVP and PLGA was a known coating option within the technical grasp of one of ordinary skill and its success would have been anticipated. In view of these teachings taken together, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an 80/20 PLGA/PVP coating as the outer skin in the invention of Chou et al. Therefore claims 22, 26, and 28-29 are obvious over Chou et al. in view of Talton, Belenkaya and Byon & Yoon.

Claims 22 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorta et al. (International Journal of Pharmaceutics 2002 248:149-156).

Dorta et al. teach a multilayered implant consisting of three stacked layers where only the center layer (core) contains drug (see page 151 section 2.3.3; instant claim 22). Each layer contains 63/37 (lactic acid to glycolic acid) PLGA (see page 150 section 2.1). The thickness of the drug free layers (film coating) is taught to be 148 μm while the composite structure has a thickness of 490 μm (see page 151 section 2.3.2 and 2.3.3; instant claims 33-34). A drug free layer thickness between 10 μm and 100 μm is not explicitly taught; however, one of ordinary skill in the art at the time the invention was made would have found it obvious to optimize the thickness of the outer drug-free layers to control and/or alter the release kinetics of the drug during the course of routine experimentation. Therefore claims 22 and 33-34 are obvious over Dorta et al.

Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maquin et al. (WO 00/33809 – see IDS) in view of Chou et al.

Maquin et al. teach an extruded subcutaneous implant composed of PLGA and peptide where the peptide is present in particle form whose sizes vary from 1 to 60 μm (see page 3 lines 3-10; instant claims 22-24). An additional skin or outer coating film is not taught present on the device.

Chou et al. teach an extruded implant that includes an outer skin (film). Such coatings are generally known to allow for added control of the release kinetics of the contained active. In particular, the outer layer of Chou et al. is taught to minimize burst release by acting as an additional barrier between the drug/polymer matrix and the aqueous outer environment (see paragraph 35). It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the outer shell

taught by Chou et al. to give additional control of the device release kinetics. Such an addition would allow the overall time for release to be varied without significantly modifying the size of the implant (see Maquin et al. page 7 lines 3-4). Therefore claims 22-24 are obvious over Maquin et al. in view of Chou et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,620,422 in view of Chou et al.

Patent 6,620,422 teach an extruded subcutaneous implant composed of PLGA and peptide where the peptide is present in particle form whose sizes vary form 1 to 60

μm (see page 3 lines 3-10; instant claims 22-24). An additional skin or outer coating film is not taught present on the device.

Chou et al. teach an extruded implant that includes an outer skin (film). Such coatings are generally known to allow for added control of the release kinetics of the contained active. In particular, the outer layer of Chou et al. is taught to minimize burst release by acting as an additional barrier between the drug/polymer matrix and the aqueous outer environment (see paragraph 35). It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the outer shell taught by Chou et al. to give additional control of the device release kinetics. Therefore claims 22-25 are obvious over claims 1-3 of U.S. Patent No. 6,620,422 in view of Chou et al.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
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